Decision Memo for Lipid Testing (Clarification of ICD-9-CM Codes for Hypertension) (CAG-00188N)

Decision Summary

CMS has determined that there is sufficient evidence to support including “any disease leading to the formation of atherosclerotic disease” in the list of indications that support coverage for lipid testing. We further determined that benign essential hypertension, as a common precursor to atherosclerotic disease, is an appropriate indication for lipid testing. Accordingly, we intend to modify the NCD list of indications that support coverage of lipid testing as follows:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease***, or any disease leading to the formation of atherosclerotic disease***
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephroitic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As follow-up to the initial screen for coronary heart disease when total cholesterol is determined to be high or borderline-high plus two or more coronary heart disease risk factors.

We also intend to modify the NCD for lipid testing to include code 401.1, benign essential hypertension, in the list of ICD-9-CM codes covered by Medicare for this service.

Pursuant to section 1869(f)(1)(B) of the Social Security Act, the term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [XVIII], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.” Thus, the addition or deletion of the ICD-9-CM codes to given services will not be subject to review under section 1869(f).

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

TO: Administrative File: CAG-00188N Lipid Testing (Clarification of ICD-9-CM Codes for Hypertension)

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RE: Coverage Decision Memorandum for Lipid Testing for Hypertension
DATE: July 17, 2003

I. Decision

CMS has determined that there is sufficient evidence to support including "any disease leading to the formation of atherosclerotic disease" in the list of indications that support coverage for lipid testing. We further determined that benign essential hypertension, as a common precursor to atherosclerotic disease, is an appropriate indication for lipid testing. Accordingly, we intend to modify the NCD list of indications that support coverage of lipid testing as follows:

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II. Background

On April 9, 2003 CMS began a national coverage determination process for clarification of ICD-9-CM codes for hypertension with regard to the lipid testing NCD. Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol and high density lipoprotein cholesterol, are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Therapy to reduce these risk parameters includes diet, exercise and medication, and weight loss, which is particularly powerful when combined with diet and exercise.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for lipid testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the lipid testing NCD, CMS determined that coverage of lipid tests was reasonable and necessary for certain medical indications. The NCD contains a narrative describing the indications for which the test is reasonable and necessary. The lipid NCD listed the following indications for lipid testing:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As follow-up to the initial screen for coronary heart disease when total cholesterol is determined to be high or borderline-high plus two or more coronary heart disease risk factors.

We also developed a list of ICD-9-CM codes that designates diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM codes covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM codes denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM codes that do not support medical necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the NCD that any ICD-9-CM code not listed in either of the ICD-9-CM sections would be categorized into group three.

We also determined that in order to add new codes to the first category which lists covered codes, a determination would have to be made that the code flows from the narrative description of indications covered or there would need to be scientific evidence to support a determination that the test should be covered for this additional indication.

IV. Timeline of Recent Activities

As discussed above, on March 10, 2000 CMS published a Notice of Proposed Rulemaking (NRPM) in the Federal Register (65 FR 13082 in which we proposed 23 NCDs as negotiated by the rulemaking committee. In response to the NPRM, we received comments requesting that we add ICD-9-CM code 401.1, benign essential hypertension, to the list of ICD-9-CM Codes Covered by Medicare for lipid testing.

On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). The preamble to the rule discusses the public comments we received. In response to the suggestion that we add code 401.1, we stated that we would be modifying the NCD to add this diagnosis to the list of ICD-9-CM codes covered by Medicare (66 FR 58796 and 58806). Unfortunately, the published NCD at 66 FR 58859 used a comma in lieu of a dash, resulting in codes 401.0 and 401.9 being included in the list of covered diagnoses, but failing to cover the intervening code, 401.1.

On April 9, 2003 we announced in a tracking sheet posted on the Medicare coverage Internet site (http://cms.hhs.gov/ncdr/trackingsheet.asp?id=94) that we had discovered this error and solicited public comments during a 30-day period. At the end of the public comment period, May 9, 2003, we had not received any comments. Since this is an internally generated request and there have been no comments from the public, external meetings have not been necessary.

V.FDA Status

Not applicable

VI. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage.

We reiterated this position in the November 23, 2001 final rule (66 FR 58795) in responding to public comments requesting the addition of numerous codes to the NCDs. The rule provides that:

“It is critical that the narrative indications for the proposed policy and the ICD-9-CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD-9-CM code that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative.”

Further, in Program Memorandum AB 02-110 we stated:

“The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. Clerical maintenance of the coding lists will be made without following the NCD process. Clerical maintenance may include such actions as revision of codes to be consistent with the annual CPT and ICD-9-CM coding updates, expansion of codes to full range of digits, and correction of code errors that may exist.”

Accordingly, in considering whether to add ICD-9-CM code 401.1, benign essential hypertension, to the list of Medicare covered codes for lipid testing we had to determine whether this code is an appropriate translation of an existing indication or whether there is scientific evidence supporting the inclusion of hypertension in the narrative portion of the NCD.

VII. Evidence

To begin analysis of this issue, we performed a literature search using PubMed and the search terms dyslipidemia, cholesterol, lipid, or lipoproteins and hypertension. Much of the literature reviewed documented hypertension and dyslipidemia as risk factors in coronary heart disease. We also reviewed the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults prepared by the National Institutes of Health, National Heart, Lung, and Blood Institute. [1] The NCEP report notes:

“Numerous observational studies have demonstrated unequivocally a powerful association of high blood pressure with risk for CHD [coronary heart disease][….] Clinical trials have established that blood pressure reduction in people with hypertension reduces risk for a variety of blood pressure-related endpoints including CHD…”

The NCEP report also noted that hypertension and high serum cholesterol often occur concomitantly.

More importantly for this review, the clinical literature indicates that the presence of dyslipidemia modifies the course of essential hypertension (together with smoking, obesity, and other factors). Citing broad research on the subject, the authors of the 14th edition of the Harrison's Principles of Internal Medicine textbook conclude that:

“Accelerated atherosclerosis is an invariable companion of hypertension. Thus, it is not surprising that independent risk factors associated with the development of atherosclerosis, such as an elevated serum cholesterol, glucose intolerance, and/or cigarette smoking, significantly enhance the effect of hypertension on mortality rate regardless of age, sex, or race […] Thus, the probability of developing a morbid cardiovascular event with a given arterial pressure may vary as much as 20-fold depending on whether associated risk factors are present. […] If coronary artery disease or associated cardiovascular risks are present, then treatment of a patient with a lower blood pressure [relative to the generally recommended threshold] may be warranted.” [2]

Hypertension and dyslipidemia independently and, to a greater extent, jointly stimulate the onset and progression of atherosclerotic disease. Thus, it is important to monitor lipid levels in hypertensive patients to ensure that they are not at increased risk of vascular disease due to other risk factors that could go undetected and untreated. Specifically, people with hypertension who also present with dyslipidemia are at higher risk for atherosclerotic vascular disease and should consequently be more closely managed (for example, treated with a tighter antihypertensive regimen than those patients with similar blood pressure and lipid levels within normal range).

VII. CMS Analysis

As noted above, we have taken the position that the ICD-9-CM Codes covered by the Medicare list are intended to contain only those codes that flow from the narrative of the indication in the NCD. Despite the fact that other hypertension codes are contained in the covered list, hypertension is not specifically identified in the narrative as an indication that supports coverage of lipid testing. However, we do believe that the evidence indicates that the combination of hypertension and dyslipidemia both is a frequent occurrence and markedly increases the likelihood and severity of atherosclerotic disease. Hypertensive patients should be tested for abnormal lipid levels so that both hypertension and dyslipidemia can be aggressively managed. Thus, we intend to modify the NCD indications for lipid testing as follows:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease, ***or any disease leading to the formation of atherosclerotic disease***
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephritic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chromic renal failure
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- As follow-up to the initial screen for coronary heart disease when total cholesterol is determined to be high or borderline-high plus two or more coronary heart disease risk factors.

We also intend to modify the NCD for lipid testing to include code 401.1 in the list of ICD-9-CM codes covered by Medicare for this service.

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1 Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *Third Report of the National Cholesterol Education Program (NCEP*). National Institutes of Health, National Heart, Lung, and Blood Institute (NIH Publication No. 02-5215). September 2002

2 G H Williams: Hypertensive Vascular Disease. Chapter 246, in Braunwald et al. *Harrison's Principles of Internal Medicine.* 14th edition. 1998.

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